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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,149	06/14/2001	John H. Kenten	2757-5	7213

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

5

Office Action Summary

Application No.

09/880,149

Applicant(s)

KENTEN ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30, 37, 40 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-30, 37, 40 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed November 20, 2003 in response to the Office Action of May 20, 2003 is acknowledged and has been entered. Claim 43 has been added. Claims 24-30, 36, 37, 40 and 43 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The rejection of claims 24-30, 36, 37, 40 and 43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention **is maintained** for reasons of record.

Applicant's arguments have been fully considered but are not persuasive. Applicant's arguments are that the E2 and E3 sequences to which the ubiquitin recognition element binds have been well defined in the art. However, the structure of the molecules to which the ubiquitin recognition element binds E2 and/or E3 does not provide any information regarding the structure of the ubiquitin recognition element itself. A review of the specification indicates that applicants have exemplified a number of ubiquitin recognition element however, there appears to be no structural similarity between those elements. The specification also indicates that new ubiquitin recognition elements may be found using the methods set out in the specification (page 30, lines

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1-3) providing further evidence that the structure of the ubiquitin recognition element is indeterminate.

The ubiquitination recognition element has only been described by its function in that it must be capable of interacting with the enzyme (receptor) of interest E2 or E3 with high specificity. If the binding interaction is not highly specific, the ubiquitination recognition element (ligand) will bind to alternative binding sites that may be present in the preparation. Non-specific binding generally is of lower affinity than specific binding (Matthews J., Fundamentals of receptor, enzyme and transport kinetics, CRC Press, Inc. (1993) pp. 28-30, 121-126, provided in prior office action). Non-specific binding of proteins to plastic has been measured to be in the range of $1-1.89 \times 10^7 \text{ M}^{-1}$ (Vallabhajosula et al. Non-specific binding of transferring and lactoferrin to polystyrene culture tubes: role of the radioligand. European Journal of Nuclear Medicine (1983) Vol. 8, No. 5, abstract only, provided with a Office action). Binding affinity of antibody-antigen binding varies a great deal from below 10^5 M^{-1} to greater than 10^{12} M^{-1} , for comparison trypsin binding to its substrate is $1.25 \times 10^4 \text{ M}^{-1}$, for antibodies affinities of less than 10^6 M^{-1} would provide a weak signal (Harlow et al. In Antibodies: A laboratory manual, ed. Harlow et al. (1988), provided with a prior Office action). A binding affinity of 10^3 M^{-1} would is not indicative of a high specificity for E2 or E3 in relation to any other protein in the cytosol of a cell because a binding affinity of 10^3 M^{-1} is deemed to be very low (see Harlow et al), this limitation is not sufficient to provide any kind of structural information regarding the ubiquitination recognition element.

Structurally unrelated “molecules” encompassed by the claimed invention other than those disclosed in the specification as filed would be expected to have greater differences in their

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structural and functional characteristics and attributes. Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required. The instant specification and claims do not provide sufficient functional and structural characteristics of the ubiquitin recognition element or the ubiquitination system coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the group comprising ubiquitin recognition element, the disclosure of particular compounds is insufficient to describe the genus of molecules, encompassed by the claimed invention. Therefore, there is lack of written description in the instant invention for the claimed method of reducing the level of a protein inside a cell.

Claims 24 and 36 recites the limitation "the ubiquitination system" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PHD.
PATENT EXAMINER 2/23/04